IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200: Joy Essman Case No. 2:12-cv-00277	
Barbara A. Hill Case No. 2:12-cv-00806	ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D.
Paula Kriz Case No. 2:12-cv-00938	MARCH 24, 2016
Brenda Riddell Case No. 2:12-cv-00547	
Sharon Carpenter Case No. 2:12-cv-00554	
Mary Jane Olsen Case No. 2:12-cv-00470	
Virginia White Case No. 2:12-cv-00958	
Sandra Wolfe Case No. 2:12-cv-00335	
Marie Smith (f/k/a Banks) Case No. 2:12-cv-01318	
Sherry Fox Case No. 2:12-cv-00878	
Lois Durham Case No. 2:12-cv-00760	
Elizabeth Blynn Wilson Case No. 2:12-cv-01286	

Daphne Barker)
Case No. 2:12-cv-00899)
)
Wendy Hagans)
Case No. 2:12-cv-00783)
)
Maria Eugenia Quijano)
Case No. 2:12-cv-00799)
)
Sharon Boggs)
Case No. 2:12-cv-00368)
)
Robin Bridges)
Case No. 2:12-cv-00651)
)
Carey Cole)
Case No. 2:12-cv-00483)
)
Cathy Warlick)
Case No. 2:12-cv-00276)
)
Donna Amsden)
Case No. 2:12-cv-00960)
)
Heather Long)
Case No. 2:12-cv-01275)
)
Penny Rhynehart)
Case No. 2:12-cv-01119)
)
Nancy Jo Williams)
Case No. 2:12-cv-00511)
)
Maria Stone)
Case No. 2:12-cv-00652)
)
Teri Key Shively)
Case No. 2:12-cv-00379)
)
Charlene Logan Taylor)
Case No. 2:12-cv-00376)
)
Tina Morrow)
Case No. 2:12-cv-00378)
)
Carol Jean Dimock)
Case No. 2:12-cv-00401)

- - -

Thursday, March 24, 2016

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Oral Deposition of CHRISTINA PRAMUDJI, M.D., taken pursuant to notice, was held at the Westin Houston, Memorial City, 945 Gessner Road, Houston, Texas, beginning at 8:13 a.m., on the above date, before Micheal A. Johnson, Registered Diplomate Reporter, Certified Realtime Reporter, and Notary Public for the State of Texas.

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INDEX
CHRISTINA PRAMUDJI, M.D.
March 24, 2016

DEPOSITION EXHIBITS
CHRISTINA PRAMUDJI, M.D.
March 24, 2016

PROCEEDINGS
CHRISTINA PRAMUDJI, M.D.
having been first duly sworn,
testified as follows:
EXAMINATION

BY MR. FAES:

Q. Dr. Pramudji, we're back on the record after an overnight break. Are you ready to proceed?

A. Yes.

Q. Doctor, before we broke last night, we were discussing some things about the Prosima and Prolift IFU, but before we get back into that, I just want to ask you a different question before I forget.

Do you do hernia repairs in your practice?

A. Abdominal wall hernia repairs?

Q. Yes.

A. No.

Q. Have you ever done hernia repairs in your medical career?

A. Yes, I have done them in my training, and maybe a small umbilical hernia

repair on a case years ago.

Q. When was that?

A. I don't know. Eight or ten years ago. We were going in for other reasons and just put in a couple of sutures at that time.

Q. Do you sometimes find, when you're repairing a prolapse, small umbilical hernias that need repair?

A. Occasionally find an umbilical hernia or an inguinal hernia. My norm is to call general surgery and have them come in and repair it.

Q. Okay. Thank you. You anticipated my next question, which is, it's your typical practice not to try to repair those small umbilical hernias yourself but to refer it out to a physician who has more experience in that area?

A. That's correct.

Q. When you -- do you recall the -- you might have already answered this. Do you recall approximately when these hernias were that you repaired, the couple

Page 147

that you did years ago?
A. I don't recall.
Q. Do you recall what -- if you used polypropylene mesh to repair those hernias?
A. On those incidental cases, that would have just been sutures. But in residency when I repaired multiple during my general surgery, and that would have been going back to 1996, 1997, then we would use mesh.
Q. Do you recall what meshes you used in 1996 --
A. No.
Q. -- at that time? But it's fair to say it wouldn't have been the Gynemesh PS in 1996 because it wasn't being made at that time, correct?
A. That's correct.
Q. So getting back to the IFU, let me ask you this, Doctor. If Ethicon said something in the IFU which Ethicon knew not to be true, would you agree that that would be wrongful?

Page 148

A. Yes. I mean, depending on -- yeah, I think if there's something that they knew not to be wrongful and it had -- it was a substantial fact, I would have to say that would be wrong.
Q. If Ethicon made claims about the mesh in the Prolift or Prosima device that Ethicon had no data to support, would that be wrongful?
A. It depends on what their -- what issues they're referring to.
Q. So your answer to that question is "it depends"?
A. That's correct, it depends.
Q. If Ethicon made claims about the mesh in the Prolift or Prosima device which it had no data to support and those claims were related to the clinical effects of the mesh, would that be wrongful?
A. It still depends on what it is. It's -- you start out with a certain body of data and then the -- you gather more data as you go along. So it depends on what the issue is.

Page 149

Q. So what -- in what situations do you believe it would not be wrongful for Ethicon to make claims about that it had no data to support?
A. I don't know. That's a very difficult question to answer. It's a hypothetical within a hypothetical, so I don't know if I could come up with any specific things.
Q. So as you sit here today, your answer to the question if Ethicon made claims about the mesh in the Prolift or Prosima device that Ethicon had no data to support, your answer to whether or not that would be wrongful would be "it depends," but you can't think of any situations, as you sit here today, in which it would be okay?
MR. GAGE: Object to form.
A. That's correct.
BY MR. FAES:
Q. Are you aware of anything in the Prolift or Prosima IFU as to which anyone at Ethicon has admitted that there was not data to support the claim about the mesh?

Page 150

A. Not that I'm aware of.
Q. If that occurred and the statement in the IFU affected the clinical performance of the mesh, would you agree that that would be a failure to provide adequate and appropriate warnings about the Prolift and Prosima devices?
A. Can you repeat the question?
MR. FAES: May I have the court reporter read it back because I don't know if I can.
(Question Read Back.)
MR. GAGE: Object to form.
A. What is "that"? What was "that" referring to at the beginning? What was the question before that?
BY MR. FAES:
Q. The previous question was about making a claim which there was no data to support, a claim about the mesh which affected its clinical performance.
A. Okay. Now, can you read the last question one more time, please.
(Question Read Back.)

Page 151

MR. GAGE: Object to form.
A. No, not necessarily. Again, it depends.
BY MR. FAES:
Q. In what situations would that not be a failure to provide an adequate and appropriate warning?
A. I can't think of any specific examples that I can give you.
Q. Are you aware of any Ethicon deposition testimony admitting anything about the mesh which is contrary to what is represented in the IFU regarding the Gynemesh PS or the devices which contain the Gynemesh PS?
A. Not that I can recall sitting here right now.
Q. If that occurred, would you agree that it would be a failure to provide adequate and appropriate warnings about the Prosima, Prolift and Gynemesh PS?
MR. GAGE: Objection.
A. No, not necessarily.
BY MR. FAES:

Page 152

Q. So it's your opinion that it's not a failure to warn, even if Ethicon provided information about the mesh it knew to be unsupported or made an affirmative representation about the mesh it knew not to be true, even if it affected its clinical performance? That's okay with you?
MR. GAGE: Object to form.
A. That's a very long question. That's correct, not necessarily. There are certain -- I can imagine certain situations where there would be -- where that would not be a problem at all.
BY MR. FAES:
Q. Okay. Let me ask you the -- strike that.
Let me ask if you -- you if the -- strike that again.
Let me ask you if the following statement is true with regard to the Prosima. Considering that native tissue repair is an option for many women, it makes sense to use vaginal mesh judiciously in vaginal mesh repairs. Is that a true statement regarding

Page 153

the Prosima?
A. It depends on the patient. So there's some patients that really need to have a mesh augmentation and some patients that can do okay without a mesh augmentation.
Q. Is your answer the same with regard to the Prolift device?
A. Yes.
Q. Is your answer the same with regard to the Gynemesh PS device?
A. Yes. Some patients really benefit from mesh augmentation, many patients.
MR. FAES: I'm going to move to strike after the answer "yes."
BY MR. FAES:
Q. So is it your opinion that even if a patient can benefit from mesh augmentation, that using -- that -- strike that.
So is it your opinion that even if a patient can benefit from mesh augmentation, it's your opinion that in those patients mesh should not be used judiciously?

Page 154

MR. GAGE: Object to form.
A. No. My opinion is that all surgeries should be done judiciously, whether with mesh or with biological graft or without mesh. Every surgery is done judiciously.
BY MR. FAES:
Q. So it's your opinion that while every surgery should be done judiciously, it doesn't make sense to use vaginal mesh judiciously for some mesh repairs if the patient can benefit from the mesh?
MR. GAGE: Object to form.
A. No, I think every surgery is done judiciously, whether using mesh or not.
BY MR. FAES:
Q. So I'm just trying to understand your opinions, Doctor. You think -- you believe every surgery should be done judiciously. Do you believe vaginal mesh should be used judiciously in every case?
A. Absolutely.
Q. Okay. Let me ask you something very specific about the Prosima IFU. What

Page 155

specific information would you say actually needed to be in there to warn doctors about complications? What do you think it needs to say?

A. Well, the only risk unique to a mesh implant is a mesh exposure or erosion. And other than that, I think they could say it has the same risks as any other pelvic surgery.

Q. So your opinion is, if the adverse reaction section of the Prosima IFU said the Prosima has the same risks as any pelvic surgery and also the risk of erosion or exposure of the mesh, that would be -- that would be a sufficient IFU with regard to the adverse reaction section?

A. Yes.

Q. But you know -- and feel free to refer to the Prosima IFU in front of you that we marked yesterday. I can't remember. We'll re-mark it as Exhibit 11 since the court reporter ran off with the exhibits yesterday.

(Deposition Exhibit 11 marked.)

Page 156

BY MR. FAES:

Q. So is it your opinion that everything else that's in this adverse reaction section is unnecessary?

A. Yes.

Q. So it's your opinion, as an expert for Ethicon, that Ethicon puts unnecessary information in the IFU?

A. That's a funny way to put it. I would say it's redundant for a pelvic surgeon that would be using this. They would know about all these risks. And someone that's using the Prosima, frankly, would know about the risk of mesh exposure. So I do -- I think -- I wouldn't say they're unnecessary. I would just say that they're redundant and just sort of extra information. I don't have a problem with it. They can put --

Q. I'm going to re-ask the question. I think you answered the question in there somewhere, but you added a lot of other things about whether you thought it was redundant or not. So I'm going to ask the

Page 157

question again, and I'm going to ask you to -- if you need to offer an explanation after the answer, do so, but if you can, please first answer the question yes or no.

MR. GAGE: Hang on a second. As I understand it, the court rules are she can answer yes, followed by an explanation; no, followed by an explanation; or she can answer, I can't answer it yes or no.

MR. FAES: I'll agree with that.

MR. GAGE: Those are the rules of court.

BY MR. FAES:

Q. So is it your opinion as an expert for Ethicon that everything in this adverse reaction section for the Prosima IFU, other than erosion exposure and the same risks as any pelvic surgery, are unnecessary?

A. I wouldn't say yes or no to that. I would say that's fine if they put that in there, but it doesn't really add anything to the knowledge of a pelvic

Page 158

surgeon.

Q. But you can't answer whether or not the -- any of the extra information is unnecessary or not?

A. That's correct.

Q. Would you agree that providing this information that -- other than -- strike that.

Would you provide [sic] that providing information in the adverse reaction section, other than just erosion exposure and the same risks as pelvic surgery, can be helpful to some surgeons in reminding them about the adverse reactions of the device?

MR. GAGE: Object to form.

A. Sure, it can be a reminder. Sort of like McDonald's coffee, be careful, it's hot, don't spill it.

MR. FAES: I'm going to move -- object and move to strike after the word "reminder."

BY MR. FAES:

Q. Doctor, I'm going to ask you about some -- a list of adverse reactions,

Page 159

and I'm going to ask you if they are potential risks of the Gynemesh PS, Prolift and Prosima device. Okay?

Is bleeding a risk of those devices?

A. Yes, it is, as with all pelvic surgery.

Q. Is hemorrhage or hematoma a risk of those devices?

A. Yes, as it is with all pelvic surgery.

Q. Is urinary incontinence a risk of those devices?

A. Yes, as with all pelvic surgery.

Q. Is urge incontinence a risk of those devices?

A. Yes, same with all pelvic surgery.

Q. Is urinary frequency, urinary retention or obstruction a risk of those devices?

A. Yes, same with other pelvic surgeries.

Page 160

Q. Is voiding obstruction a risk of those devices?

A. Yes, same with other pelvic surgeries.

Q. Acute and/or chronic pain?

A. Yes, same with other pelvic surgeries.

Q. Wound dehiscence?

A. Yes, same as other pelvic surgeries.

Q. Nerve damage?

A. Yes, same as other pelvic surgeries.

Q. Recurrent prolapse?

A. Yes, same as other pelvic surgeries.

Q. Foreign body response?

A. Yes, same with other pelvic surgeries.

Q. The potential to impair normal voiding function for a variable length of time?

A. Yes, same as other pelvic surgeries.

Page 161

Q. Pelvic pain or pain with intercourse which in some patients may not resolve?

A. Yes, same as other pelvic surgeries.

Q. Excessive contraction or shrinkage of the tissue surrounding the mesh?

A. Yes. And that -- you can have excessive contraction even without mesh.

Q. Punctures or lacerations of vessels, nerve structures or organs, including the bladder, urethra or bowel which may occur and may require surgical repair?

A. Yes, same as other pelvic surgeries.

Q. Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area which may occur?

A. Yes, same as other pelvic surgeries.

Q. And all of these adverse reactions may require surgical treatment?

A. Yes, the same as other pelvic

Page 162

surgeries.

Q. Is it your opinion that all of those risks that I just read to you are unnecessary to be included in the Prolift, Prosima or Gynemesh IFU?

A. That's correct. They are part of the body of knowledge of pelvic surgeons, so I think they don't necessarily have to be in there.

Q. Do you know whether or not those risks are in the Gynemesh PS IFU today?

A. I would have to review it. I don't have a problem if they're in there.

Q. Do you know whether or not all of the adverse events I just read to you were added in 2015?

A. I would have to look at it. I don't know.

(Deposition Exhibit 12 marked.)

BY MR. FAES:

Q. I'm going to hand you what's been marked as Exhibit No. 12 to your deposition.

MR. FAES: Do you want one,

Page 163

William?
MR. GAGE: Yeah. Thank you.
BY MR. FAES:
Q. So I'll represent to you that those are all risks that were added to the Gynemesh PS IFU beginning with this revision that Ethicon released in 2015, and the front page of this is dated February 3rd, 2015.
Do you know whether or not these are all risks of the Prosima, Prolift and Gynemesh PS device that Ethicon knew about when those devices were first launched onto the market?
MR. GAGE: Object to form.
A. I'm not sure. I don't know.
BY MR. FAES:
Q. Do you know whether or not Ethicon could've chosen to include all of these risks in their IFU --
A. I would --
Q. -- from the -- sorry, I wasn't done with the question. I'll start over.
Do you know whether or not Ethicon could have chosen to include all of

Page 164

these risks in their IFUs for the Gynemesh PS, Prolift and Prosima device beginning from the first day that they were launched in the United States?
A. I would have to say, sure, theoretically, you could come up with a long laundry list of things that you could put in the IFU. So, sure, theoretically they could have put them in from the beginning.
Q. Do you know whether or not Ethicon felt it was necessary to add these adverse events to their IFU in 2015?
A. No, I don't know what they thought.
Q. Do you believe, as an expert for Ethicon, that Ethicon would knowingly put things in the IFU that it believed to be unnecessary?
MR. GAGE: Object to form.
A. Can you read back the question or can you repeat it?
BY MR. FAES:
Q. I'll repeat it. Do you believe, as an expert for Ethicon, that

Page 165

Ethicon would knowingly put things in the IFU that it believed to be unnecessary?
MR. GAGE: Object to form.
A. I don't know what they knew or didn't know.
BY MR. FAES:
Q. Now, you -- strike that.
You testified that it was your typical practice to read the IFU before implanting the device for the first time, right?
A. Correct.
Q. And you typically wouldn't re-review the IFU unless you were aware that there was a change to that IFU, correct?
A. That's correct.
Q. Would you have any way of knowing, unless you closely examined the IFU, that there had been an important IFU update?
A. Not that I'm aware of.
Q. Do you think it would be -- strike that.
You're a past user of Gynemesh PS, correct?

Page 166

A. Correct.
Q. Do Ethicon sales reps know that you've used Gynemesh PS and products that contain Gynemesh PS in the past?
A. Yes.
Q. Has anyone from Ethicon ever informed you that the IFU for the Gynemesh PS was updated in 2015?
A. No, and I wouldn't expect them to. If you have a surgeon that's familiar with the product, they're having good results, it's not going to change anything.
Q. Isn't it possible that there are -- strike that.
Do you think it would be a reasonable thing to do, for Ethicon to inform doctors that there is a new IFU for its products out there that may contain important adverse reactions that were not contained in the previous IFU?
A. Sure, it's reasonable. I wouldn't say that's unreasonable.
Q. Do you think it would be helpful for Ethicon to inform doctors that

Page 167

there's a new IFU out there for its products that may contain important adverse reactions that were not contained in the previous IFU?
A. Not particularly, because we already know about all this.
Q. So you believe that every surgeon in America knows about all of the new adverse reactions that were added to the Gynemesh PS IFU in 2015?
A. Did you mean to say "every surgeon" or "every pelvic surgeon"?
Q. I'll restate it as every pelvic surgeon. So you believe that every pelvic surgeon in America knows about all of the new adverse reactions that were added to the Gynemesh PS IFU in 2015?
A. Well, I don't know what they would know about the IFU. But I would say that a pelvic surgeon that is familiar with pelvic surgery, familiar with mesh, would definitely be aware of these adverse reactions.
MR. FAES: I'm going to object and move to strike after the word

Page 168

"IFU."
BY MR. FAES:
Q. Have you done any kind of research or survey to determine -- strike that.
Have you done any kind of research or survey or study to determine what the typical pelvic surgeon in the United States knows about the adverse reactions of the Gynemesh PS, Prolift and Prosima device?
A. No, I haven't done any research like that.
Q. If there were an important update to the indications for use for a particular medical device, do you think that would be something that would be reasonable for a medical device company to communicate to surgeons who they knew used the device?
A. Depends on what you mean by "important." Who considers it important? The surgeons or the attorneys?
Q. Well, you know that the -- I'm not -- okay. Let me ask it this way. If there were a update to the indications for

Page 169

use for a particular medical device that the FDA deemed important, do you think that that would be something that would be reasonable for a medical device company to communicate to surgeons who they knew used the device?
A. Again, it depends what it is, depends if it's going to affect how you implant it, you use it and what the nature of the update is.
Q. I think yesterday you testified that you believe the Gynemesh PS was still indicated for transvaginal placement.
A. I believe it is.
Q. Do you want to take a moment to read the indications for use in this updated 2015 IFU and tell me if you -- after reviewing that, if you still believe that's the case?
(Witness Reviews Document.)
A. It says here that it's "indicated as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted."

Page 170

So apparently they're using it more for intraabdominal for that indication at this point. So I was not aware of that change.
BY MR. FAES:
Q. Were you aware that this change actually occurred not with the 2015 IFU but with the 2013 IFU?
A. No, I didn't know about that.
Q. So you didn't know, as an expert offering opinions on the Gynemesh PS mesh, that the indications for use for the device changed nearly three years ago?
A. No.
MR. GAGE: Objection.
A. As I mentioned, I haven't used Gynemesh for several years, so I was not aware of that.
BY MR. FAES:
Q. Since the indications for use for the Gynemesh PS mesh have changed as of 2013, would it be reasonable to assume that indications for use for the Prosima and Prolift device would have changed as well if

Page 171

those products were still on the market?
MR. GAGE: Object to form.
A. I don't think so because those are specifically transvaginal kits. So I don't know what other indication that they could put besides transvaginal placement.
BY MR. FAES:
Q. But you know that the FDA has told Ethicon that they can no longer sell the Prosima or Prolift device unless they complete a 522 order, correct?
A. I believe that's correct.
MR. GAGE: Object to form.
BY MR. FAES:
Q. And you know that the FDA agreed that the Prolift and Prosima 522 plans could be placed on hold if Ethicon -- if Ethicon agreed not to sell those devices anymore, correct?
A. I don't know about those details.
Q. You don't know about those details?
A. No.

Page 172

Q. Are you aware that if Ethicon decides to start selling those devices again, they need to notify the FDA before doing so?
A. I don't know about that detail either.
Q. Assuming that that's true, do you think it's reasonable, since it's been three years -- over three years since the Prosima and Prolift devices were sold and the FDA has changed -- had -- strike that.
Assuming that's true, do you think it's reasonable to assume that since it's been three years since the Prosima and Prolift device has been sold and the indications for use for the mesh that is used in those devices has changed in that time, that the FDA would look closely at the IFUs for those devices before allowing that to be put -- placed back on the market?
MR. GAGE: Object to form.
A. I would imagine that they would, but I don't know what the FDA process is in detail.

Page 173

BY MR. FAES:
Q. Do you know that -- whether or not Ethicon negotiated with the FDA to keep Gynemesh PS on the market, and a condition of their being allowed to keep it on the market was to remove the transvaginal indication for the Gynemesh PS and have it be indicated for abdominal placement only?
MR. GAGE: Object to form.
A. I don't know about that.
BY MR. FAES:
Q. Do you think that would be an important fact to consider in forming your opinions in this case?
A. No, I don't think that would affect my opinion.
Q. Do you think a surgeon who has been using the Gynemesh PS transvaginally prior to the IFU update in 2013 would want to know about the indication-for-use change if he were going to continue using it after the indication-for-use change in 2013?
MR. GAGE: Object to form.
A. I think if a surgeon is using

Page 174

it and is comfortable with it, having good results with it, even transvaginally, it's not important for them to know.
BY MR. FAES:
Q. So it's your testimony that you, as a physician, wouldn't want to know if you were using a medical device off label before you used it off label?
A. If you're using something with good results, literature supports safety and efficacy, I think the change of -- the off-label change of indication is simply, really, semantics in that situation and, yeah, it -- I guess you could say it would be helpful to know. But I think you would still be able to support your use of the device off label based on your own results and based on the literature that's out there.
MR. FAES: I'm going to object and move to strike just because I'm not sure what your answer there was. Maybe it's my fault. Maybe I asked a bad question, so I'll ask it a little bit differently.

Page 175

BY MR. FAES:
Q. Would you, as a physician, want to know if you were using a medical device off label before you used the device?
A. Not necessarily.
Q. Do you think other physicians would want to know if they were using the device off label before they used that device?
A. Not necessarily. I can certainly conceive of how this -- how you could continue using this off label and feel very comfortable and be able to support your position for using it off label, even if you found out after the fact.
Q. So is it your opinion -- strike that.
So is it not your typical practice to read the instruction -- strike that.
Is it not your typical practice to read the indications for use for a medical device before deciding how to use that medical device?

Page 176

A. Like I said before, when you first use something, you review the IFU. But after you use it and you're comfortable with it, you apply your skills as a surgeon. That's what's more important, not -- we don't live and die by the IFU. We don't function based on the IFU. We function based on our skills and training.
MR. FAES: I'm going to object and move to strike. Again, I may have asked a bad question so I'll try to ask it a little bit better.
BY MR. FAES:
Q. Is it your typical practice to read the indications for use for a medical device before deciding how to use that medical device?
A. No. I don't use it to decide how to use the medical device. I use it to make sure I understand what the device offers, make sure I understand how it's intended for use.
Q. Do you think it's typical practice for other pelvic surgeons to read

Page 177

the indications for use for a medical device before deciding how to use that medical device?
A. I don't know the answer to that question. I don't know how many surgeons look at the IFU. I don't know. Because a lot of training you learn from other surgeons. We rarely learn from the IFU.
MR. FAES: I'm going to object and move -- move to strike after the third "I don't know."
BY MR. FAES:
Q. Is it your testimony that the indications for use in the IFU don't guide your decision on how to use that device?
A. To a certain degree it may guide how I use the device, but it's really not the primary thing that I rely on, if that makes sense. It's sort of supplemental. Okay, let's see what it says here, see if there's any nuance that I'm not aware of, and then proceed as such.
Q. Would you agree with me that if a physician were to place the Gynemesh PS

Page 178

transvaginally today in a surgery in the United States, that use would be off label?
A. Yes, that's correct.
Q. Would you agree with me that if a physician were to place the Gynemesh PS transvaginally today in the surgery -- strike that.
Would you agree with me that if a physician were to place the Gynemesh PS transvaginally today in the United States, that would be contrary to the indications for use as currently stated in the IFU?
A. Yes, I would have to agree with that based on what the IFU says here.
Q. I think I'm done with that for now. You can set that aside.
Doctor, I'm going to mark another copy of your --
MR. GAGE: FYI, the Wolfe depo has been postponed. I just got the e-mail.
MR. FAES: Exciting news. Do you have another copy of her op report, William?

Page 179

(Discussion Off The Record.)
BY MR. FAES:
Q. Doctor, I'm just going to ask you -- I'm going to want to ask you a few questions about your pelvic organ prolapse report. If you need to refer to -- back to it, the court reporter took off with it. I can give you my copy if you really need it.
MR. GAGE: Well, but you had it in your notebook, didn't you?
THE WITNESS: That big one. I think it might be that one on the top.
BY MR. FAES:
Q. I think you can probably answer these questions without looking at it, but I don't want you to be handicapped by not having it available.
MR. FAES: Yeah, we're still on the Prolift deposition.
BY MR. FAES:
Q. Now, in your report in your reliance list, there's medical literature that you cite in both your report and on your reliance list. Have you read all those

Page 180

articles?
A. I've at least perused them. I wouldn't say that I've read them all in detail.
Q. Would you agree that the list of medical literature and articles in your report and your reliance list is not a comprehensive list of all the articles and literature that's available on the Prosima, Gynemesh PS or Prolift?
A. Probably not.
Q. Is it possible there's clinical data that you didn't see, which, if you saw, could change your opinions in this case?
MR. GAGE: Object to form.
A. It's possible there's literature I haven't seen, but I think I've got the -- most of the level 1 literature, so I doubt there's something that would change my opinions.
BY MR. FAES:
Q. Would you agree with me that unless you see such data, you can't assess whether it's significant to you in forming

Page 181

your opinions in this case?
A. It depends on what it is.
Q. But you would agree that it's possible that there could be literature or data out there that could change your opinions in this case and you can't know whether it's significant unless you see it, correct?
MR. GAGE: Object to form.
A. No, I would disagree. I think that's very unlikely because I feel very comfortable with the literature that I have here and my own experience. My opinions are very firm.
BY MR. FAES:
Q. So you believe it's very unlikely. But do you believe it's possible?
A. I think it's next to impossible.
Q. I'm just going to leave that alone.
(Deposition Exhibit 13 marked.)
BY MR. FAES:
Q. Just so you have it, Doctor,

Page 182

I'm going to -- you're going to need this eventually for your TVT deposition later anyway, I'm going to re-mark a copy of your reliance list for all your expert reports as Exhibit 13 for the record.
A. Okay.
Q. Now, there's a lot of different articles that you cite in your Gynemesh PS, Prolift and Prosima report. Did you deliberately not cite to articles that were not favorable to those products?
MR. GAGE: Object to form.
A. No, I didn't deliberately. I tried to pick out the articles which I thought had the best data as far as the most rigorous data, whether it was favorable or not.
BY MR. FAES:
Q. I'm going to shift gears a little bit, Doctor, and ask you some questions about the mesh properties of the Gynemesh PS, Prolift and Prosima device.
Do you know whether or not the amount of mesh placed in a woman's pelvis for

Page 183

the treatment of prolapse has an effect on the intensity and duration of the foreign body reaction and inflammatory response?
A. I would say that the more sutures, the more mesh, the more foreign body -- it is a foreign body that's placed, you're going to have more of a foreign body reaction.
Q. So you would agree that, in general, the larger the amount and weight of the material, the greater the foreign body reaction and inflammatory response will be?
A. Yes. More than likely. However, that doesn't necessarily -- that's a normal reaction that you would expect. It's part of the wound healing.
MR. FAES: I'm going to object and move to strike after the word "likely."
BY MR. FAES:
Q. Doctor, am I correct that you don't hold yourself out to be an expert with regard to the design of medical device -- strike that.

Page 184

Doctor, am I correct that you don't hold yourself out to be an expert with regard to the design of medical device kits for the treatment of prolapse?
A. I would say that I am somewhat of an expert in that area as far as being a user of the devices and also being involved in some of the labs that are held during the development of devices that I've been involved in. So as far as being asked to evaluate different devices as they're being produced, as far as that goes, I do have some expertise in that area.
Q. Well, let me see if I can ask it a different way. Am I correct that I would not expect you to offer design -- strike that.
Am I correct that I would not expect you to offer opinions on the design of the Prosima?
MR. GAGE: Object to form.
A. My opinions would go to how I feel the design is based on use in my hands and based on the patient results. So I feel

Page 185

very confident and familiar with evaluating the design based on those parameters.
BY MR. FAES:
Q. Is that the extent of the opinions that I would expect you to offer on the Prosima -- on the design of the Prosima, rather?
MR. GAGE: Object to form.
A. I may have some other opinions as far as they go to the mesh in general or pelvic floor kits or surgery in general.
BY MR. FAES:
Q. So you would have opinions on the design of the mesh in general or the design of pelvic floor kits and surgery in general?
A. Yes.
Q. Would those opinions on the design go beyond how those devices -- you believe those devices worked in your hands?
A. Yes, they potentially could.
Q. Well, you understand, Doctor, that this is my opportunity here today to learn what your opinions in this case might

Page 186

be. What other opinions might you offer on the design of the Prosima or mesh kits or mesh in general?
A. Well, opinions about the design of the mesh in general, the way that the mesh is configured, the size of the pores, the materials that the mesh is made of. Or with the kits, how they're designed, how they -- the development of the kits, the nuances of the trocars and how it worked in patients.
Q. Have you ever worked on the design team for a medical device?
A. No, only on a consulting basis.
Q. Am I correct in that you're not a biomedical engineer?
A. I'm not a biomedical engineer. I studied it, but I'm not a biomedical engineer.
Q. Do you hold yourself out as an expert in biomedical engineering?
A. To the degree that it applies to my practice, yes.
Q. Do you know what a design failure modes analysis is?

Page 187

A. I don't -- I'm not familiar with that term.
Q. Is it fair to say that you have never reviewed any design failure mode analysis with respect to the Prosima, Gynemesh PS or Prolift?
A. I may have, because just breaking down that terminology, I don't -- I can't give you a quick definition. But just breaking it down, it sounds like it's just testing the failure of the design with some -- probably some mechanical stretching or that sort of thing, but that's my conjecture. So I may have read about that.
Q. Do you know what a process failure modes effects analysis is?
A. I'm not familiar with that term.
Q. Do you recall if you reviewed any process failure modes effects analysis with the Prosima, Prolift or Gynemesh PS devices?
A. I'm not sure.
Q. Do you know what an

Page 188

applications failure modes effects analysis is?
A. I'm not sure.
Q. Do you recall if you've reviewed any of those for the Gynemesh PS, Prolift or Prosima device?
A. I'm not sure.
Q. Do you hold yourself out as having expertise or specialized knowledge regarding the type of mesh used in the Prosima, Prolift -- I guess I'll say Gynemesh PS device even though the mesh -- that's the only thing in the Gynemesh PS device is the mesh?
A. Could you repeat the first part of the question?
Q. Yeah, I'll re-ask it because I didn't think it through before I asked it.
Am I correct in that you don't hold yourself out as having expertise or specialized knowledge regarding the type of mesh used in the Prosima or Prolift device?
MR. GAGE: Object to form.
A. No, that's incorrect because I

Page 189

feel very knowledgeable about the type of the mesh, the use of the mesh, behavior of the mesh.
BY MR. FAES:
Q. Do you have any expertise or specialized knowledge regarding whether or not a 1-millimeter pore size when the mesh is used in the body has any advantages or disadvantages for the patient?
A. Yes. I've definitely studied the pore sizes and I've seen how the mesh behaves in the patients, and I feel like I have a very in-depth knowledge about that.
Q. Let me ask you this. Do you believe that it's important for a mesh to have a pore size of 1 millimeter or greater in all directions in order for the mesh to be properly incorporated into the tissues once it is placed?
A. No, I don't think it has to be exactly 1 millimeter. Neutrophiles and the vagina itself are much smaller than that, so it doesn't need to be near that size to incorporate well and to heal that well.

Page 190

Because as you know, when we put it in, the pores are going to deform somewhat. That's to be expected. And even with that, the patients clinically heal well and do well with good incorporation.
Q. Do you believe -- you just stated that you know that the mesh is at times going to deform. Strike that.
You just stated that you know at -- sometimes that the mesh is going to deform. Do you believe the mesh can deform to the point where the pores are too small for good tissue incorporation?
A. No, I don't think so. I think that the cells are microscopic. So they're going to be able to get into -- between the fibers, no matter what.
Q. You stated that you don't think it's necessary to have a pore size of 1 millimeter in all directions. What pore size do you think is required in order for the tissue to be incorporated into the body?
MR. FAES: You want to take a quick break? I need to run to the

Page 191

restroom anyway. Let's go off the record.
(Recess Taken From 9:09 a.m. To 9:16 a.m.)
BY MR. FAES:
Q. Doctor, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. When we took a break, there was a question pending. It looked like you were looking at your report, so I'll restate it.
You stated that you don't think it is necessary to have a pore size of 1 millimeter in all directions. What pore size do you think is required in order for tissue to be incorporated into the body in pelvic organ prolapse surgery with mesh?
A. So the Amid classification has a pore size of greater than 75 microns.
Q. So if I understand you correctly, you're relying on the Amid standard for your opinion on how large the pore size needs to be?

Page 192

A. Yes. But even if it were a little smaller than that, it would be fine because the neutrophiles and the macro fascias are much smaller than that. So even if it got to a form lower than that, they should be able to come in and lay down the collagen and the scar tissue and incorporate the mesh.
Q. You know that the Amid standard came out in 1998, correct?
A. Correct.
Q. And you know that it was originally developed for guidance in hernia repair, correct?
A. I believe so.
Q. Do you know whether or not Dr. Amid thinks that his standard applies to the type of mesh used in pelvic organ prolapse and stress urinary incontinence products?
MR. GAGE: Object to form.
A. I don't know what he thinks, but it's been widely adopted and utilized successfully by the pelvic floor literature.

Page 193

MR. FAES: I'll object and move to strike after the answer "thinks."
BY MR. FAES:
Q. Do you know what Ethicon -- strike that.
Do you know whether or not Ethicon scientists and engineers think that the Amid standard is outdated?
MR. GAGE: Object to form.
A. I don't know what they think about that.
BY MR. FAES:
Q. Do you know if -- whether or not Ethicon scientists and engineers thought the Amid standard was outdated as early as 2005?
MR. GAGE: Object to form.
A. No, I don't know about that.
BY MR. FAES:
Q. You know that the Amid standard was originally developed for hernia repair. Do you know whether or not the FDA told Ethicon that they don't believe that they can leverage their hernia experience for the

Page 194

pelvic organ prolapse products?
MR. GAGE: Object to form.
A. I don't know about that.
BY MR. FAES:
Q. If Ethicon scientists, engineers and consultants believed that the pore size of the mesh in the Prosima and Prolift products needed to be 1 millimeters in all directions in order for proper tissue integration to occur, you would disagree with them, correct?
A. I think it doesn't have to be 1 millimeter. It could be smaller. But I think 1 millimeter is fine. It works great.
Q. So is the answer to my question yes, if they thought it needed to be a minimum of 1 millimeter in all directions in order for proper tissue integration to occur, you would disagree with them?
A. Yes, I would disagree.
Q. Are you forming your opinions on the assumption that the only standard for pore size that matters is 75 microns?
A. No.

Page 195

Q. What other pore size do you think matters?
MR. GAGE: Object to form.
A. Well, I'm forming my opinion based on what has been used and what works and what I've seen in my clinical practice. So not just on the pore size.
BY MR. FAES:
Q. But regard -- with regard to the pore size which is needed for proper tissue integration, is the only guideline that you are relying on 75 microns?
A. That's the main thing I'm relying on because I think that's what the majority of pelvic floor science relies on.
Q. Is there any other numerical or quantitative guideline that you're relying on for the size the pores need to be in the mesh in order for proper tissue integration?
A. Not that I can think of right now.
Q. Have you ever specifically studied the question of whether or not a 1-millimeter pore size under strain is of any

Page 196

significance with the Prosima, Gynemesh PS or Prolift devices?
A. Did you say "under strain"?
Q. Yeah, I'll re-ask the question. Have you ever specifically studied the question of whether or not a 1-millimeter pore size under strain is of any significance with the Prosima, Gynemesh PS or Prolift devices?
A. What do you mean by "under strain"?
Q. I mean when the mesh is put -- placed under stress or deforms.
A. I believe I did look at some articles that look at that and look at the -- what happens to the pore sizes when they are under strain. Whether that applies to clinical practice or not, I don't think so. There's going to a little bit of strain and deforming, but if the mesh is placed properly without tension, then the pore sizes will be minimally deformed. Does that answer your question?
Q. Yeah, I think so. Might have

Page 197

some follow-up questions, but I think you answered the question.
A. Okay.
Q. Would you agree that even if the Prosima or Prolift device is placed perfectly by the surgeon, that the pore sizes can still become deformed or stretch or be put under strain?
A. Yes, they can.
Q. Does the -- do you know if the term "scar plating" had any significance for Ethicon internally among doctors and scientists?
MR. GAGE: Object to form.
A. I don't know.
BY MR. FAES:
Q. Would you agree that when the mesh goes through the process of creating scar tissue and fibrosis on the mesh, those processes can also be accompanied by contraction of the mesh?
MR. GAGE: Object to form.
A. It's designed to have fibrosis and scarring to incorporate the mesh and

Page 198

you'll have some mesh contraction, but again, I dispute the term "mesh" -- you'll have scar contraction, but I dispute the term "mesh contraction."
BY MR. FAES:
Q. So you dispute the term "mesh contraction" even though the Gynemesh PS IFU specifically warns excessive contraction or shrinkage of the tissue surrounding the mesh as a potential adverse event in the Gynemesh PS?
MR. GAGE: Object to form.
A. It says -- again, it says, "Excessive contraction or shrinkage of the tissue surrounding the mesh." I think that's the same thing that I said.
BY MR. FAES:
Q. But we -- as we've agreed, if the tissue surrounding the mesh contracts, it can take the mesh with it --
A. Yes.
Q. -- meaning the mesh can contract as well.
A. It's semantics. Yes, the mesh

Page 199

can be incorporated into the scar tissue, but the mesh itself is not contracting.
Q. Do you know who the inventor of the Prosima device is?
A. I believe it was Dr. Marcus Carey.
Q. Have you ever met Dr. Carey?
A. I don't think so.
Q. Do you know that -- whether or not Dr. Carey receives royalties each time the Prosima device is sold?
A. I don't know.
Q. So I take it since you don't know whether or not he receives royalties, you don't know how much he's been paid in royalties with regard to the Prosima?
A. No. But he should get paid because it's a great invention. He should get paid for his intellectual knowledge -- his intellectual property, I should say.
MR. FAES: Object and move to strike after the answer "no."
BY MR. FAES:
Q. Do you know if he's been paid

Page 200

over $2 million in royalties for the Prosima device?
MR. GAGE: Object to form.
A. I don't know.
BY MR. FAES:
Q. Do you know he was the lead author on the Prosima study done by Ethicon prior to launch?
A. Yes.
Q. Do you know what his personal success rate that he reported with the Prosima was in that clinical study at his site?
A. At his site alone?
Q. Yes.
A. No, I don't know.
Q. Do you know if it was 100 percent? Would that -- would you be surprised to learn that he -- strike that.
Would you be surprised to learn that Dr. Carey reported a 100 percent success rate with the Prosima at his site?
A. No. It could be possible based on patient selection.

Page 201

Q. Do you know that some other investigators in that study reported a zero percent success rate with the Prosima at their site?
A. No, I'm not aware of that.
Q. Do you think the fact that Dr. Carey was the inventor of the product and was going to receive royalties for each Prosima device that he sold injected bias into the study where he was the lead investigator?
A. I think every investigator has a bias. So, yes, of course, he's going to have his own bias.
Q. Do you know whether or not Ethicon believed that there was a fair amount of spin going on regarding Dr. Carey's reporting of his data?
A. I don't know.
MR. GAGE: Object to form.
BY MR. FAES:
Q. Have you ever seen any documents or correspondence between Ethicon indicating that that was the case?

Page 202

A. I don't recall having seen that.
Q. Now, you've stated that you don't believe that shrinkage of the mesh occurs; it's contraction of the tissues surrounding the mesh, correct?
A. Correct.
Q. Are you familiar with the Fatton article, which I believe is cited in your reliance materials?
A. How are you spelling that?
Q. F-a-t-t-o-n.
A. I would have to review it again. Not off the top of my head.
Q. Well, let me ask you this. Do you recall in that study that they reported a 17 percent shrinkage rate at three months?
A. I would have to look at it.
Q. So you don't recall as you sit here today?
A. I don't recall.
Q. Would you agree that -- assuming they did report a 17 percent shrinkage rate at three months, that that's a

Page 203

significant shrinkage rate?
MR. GAGE: Object to form.
A. I would say that that is within the norm for pelvic surgery to have 17 percent shrinkage of the scar tissue. You would want to have some shrinkage of the scar tissue in order to have a good repair. And 17 percent sounds reasonable to me.
BY MR. FAES:
Q. But would you agree that a 17 percent shrinkage rate is clinically significant and could have clinical impact to the patient?
A. Yes, I think it would have a good clinical impact because they're going to have better support and -- better support of the vaginal wall.
Q. So you believe that -- do you believe that shrinkage of the mesh or contraction of the tissue surrounding the mesh is a positive thing?
A. Yes. It's desirable.
Q. Do you believe that's true in all cases, or do you believe that there's

Page 204

instances where contraction or shrinkage of the mesh can cause pain or can cause the device to migrate?
A. Oh, yes, I think it's clear that you're going to have some patients that heal with exuberant scar tissue, nerve endings get involved and they would have more pain. That can also occur with plication or sacrospinous ligament fixation or uterosacral ligament fixation, so it's not unique to mesh.
MR. FAES: I'm going to object and move to strike after the answer ending with "pain." I didn't ask about plication or sacrospinous ligament fixation or any of that.
BY MR. FAES:
Q. Are you aware of any clinical data reported by the French transvaginal mesh group regarding the percentage of women treated with Prolift suffering from painful mesh contraction with the Prolift?
A. I believe I've seen that. I can't cite it right now without looking

Page 205

through things.
Q. Have you relied on data and literature published by Dr. Cosson and the TVM group to support your opinions that the Prolift and Gynemesh PS is safe and effective?
A. Yes.
Q. Do you know whether or not Dr. Cosson is considered the inventor of the Prolift?
A. I believe he is.
Q. Have you ever met Dr. Cosson?
A. No.
Q. Never been to France?
A. No.
Q. Do you know if Dr. Cosson receives royalty on the Prolift like Dr. Carey?
A. I don't know.
Q. Do you know if Dr. Cosson has also received over $2 million in royalties for the Prolift device?
A. I don't know.
Q. Would you agree that the fact

Page 206

that Dr. Cosson was the inventor and received royalties, that that would inject potential bias into any study he was involved in?
A. I would give the same answer before, that every investigator has some bias to some degree. So I would not be surprised if there were some bias there.
Q. So is the answer to my question yes, you would agree that Dr. Cosson would have potential bias in any reporting of any studies that he was involved in with the Prolift?
A. Yes, there's a potential for bias there.
Q. Are you familiar with committee opinion 513, the joint opinion of ACOG and AUGS?
A. Can I take a look at it?
Q. I don't have -- I don't have a copy with me here. I'm just asking you, are you familiar with it?
A. I don't know of one by name -- by that name.
Q. Okay. Well, I'll represent to

Page 207

you that a portion of the committee opinion said that the mesh kit should only be used in high -- strike that.

I'll represent to you that a portion of the committee opinion says that mesh kits should only be used in high-risk individuals for which no other options are available or appropriate.

Do you agree or disagree with that opinion?

MR. GAGE: Object to form.

A. At this point I would agree, given the current legal environment, I think, although we had great success in patients that weren't as high risk or that was their first option. But unfortunately in this current legal environment, I would have to agree with that statement.

BY MR. FAES:

Q. You say "in this current environment." At what point do you believe -- strike that.

You indicated -- is there -- strike that too.

Page 208

Is there a point at which you would not have agreed with that opinion, a point in time, and when did that -- when did your opinion change that you agree with the opinion?

A. Probably around the time that there started to be a lot of attorney advertising, soliciting patients, that created a negative environment around mesh surgery. So I think that was 2012, somewhere around there.

Q. So up until 2012 you would have disagreed with that opinion; is that accurate?

A. That's correct.

Q. And after 2012 you agree with that opinion?

A. To a degree, yes.

Q. Is it your testimony that you only agree with that opinion now because of the legal environment?

A. That's correct.

Q. So it's not based on medical judgment on your -- based on your medical judgment, you disagree with that opinion?

Page 209

A. Right. Based on my medical judgment, I still think that transvaginal mesh repairs are very effective, very safe and very beneficial to women, even if they're not high risk, even if they haven't failed a prior procedure. And that's based on the literature and based on my own experience.

Q. Is the -- as you called it, the legal environment the only reason why you agree with that opinion today?

A. Yes.

Q. So the recent FDA actions and reclassifying pelvic organ prolapse products to a class III high-risk device and issuing a public health notification in 2008 and 2011 have no bearing on that opinion?

A. No.

Q. Do you agree that the Prolift should only be used in women for whom other approaches and other alternative approaches are not reasonable? I think I asked a bad question. I'm going to strike that and re-ask it.

Page 210

Do you agree that the Prolift should only be used in women for whom other alternative approaches are not reasonable?

MR. GAGE: Object to form.

A. Well, the Prolift isn't available anymore, so I'm not sure how to answer that question.

BY MR. FAES:

Q. When the Prolift was available, would you agree that it should have only been used in women for whom other alternative approaches are not reasonable?

A. No.

Q. Same question on the Prosima?

A. No. I feel like I was asked a lot of these questions before in the Prolift deposition.

Q. You've stated some questions -- stated some opinions about the current legal environment regarding mesh devices and products. Do you know how many mesh lawsuits have been filed in the United States at this point?

A. I don't know the number.

Page 211

Q. Do you believe that all of the mesh suits filed in this country are unfounded?
A. That all of them are unfounded? Well, based on the claims of mesh defect and failure to warn, I would say yes because there's not a mesh defect; there's not a failure to warn.
Q. So if there were over 70,000 individuals in the United States that had filed legal claims against the manufacturers of mesh products, you believe that all of those claims are unfounded?
A. Based on the claims, yes.
Q. Do you -- you would agree that the Prosima device is supposed to be placed without tension; is that correct?
A. That's correct.
Q. Do you know what Ethicon thought as to whether or not most doctors understood the tension-free concept in connection with the Prosima?
MR. GAGE: Object to form.
A. No, I don't know what they

Page 212

thought.
BY MR. FAES:
Q. Do you know what Ethicon thought as to whether or not most doctors understood the vaginal support device concept in connection with the Prosima?
MR. GAGE: Object to form.
A. No, I don't know what they thought.
BY MR. FAES:
Q. And you don't know whether or not most doctors understood it or not; is that correct?
A. Right, I couldn't comment on that.
Q. You would agree that if the tension-free concept with the Prosima was not understood and mesh ended up under tension after the procedure, that could increase the risk of erosions, right?
A. No, I wouldn't say that. I don't think that that would cause erosion. Erosion occurs when the mesh is not placed in the proper plane.

Page 213

Q. Let me ask a different question. Would you agree that if the tension-free concept was not understood and mesh ended up under tension after completion of the Prosima procedure, that could increase the risk of complications, correct?
A. That could, yes.
Q. Could it increase the risk of treatment failure?
A. No. I think the risk that I think of is potentially pulling on the tissue and the scarring pulling and causing pain. That's the issue I think of with tension.
Q. Would you agree that even if a doctor is fully trained and follows the Prosima technique perfectly, he can end up with tension on the mesh that can lead to complications?
A. That -- yes, that can occur. The patient can wake up and cough and that can pull things, or the way that they heal, they have exuberant scar tissue and that can cause tension.
Q. Are you aware of any monogragh

Page 214

for the Prosima device like there is for the Prolift device?
A. I can't recall if I have seen that or not.
Q. Same question with regard to the Gynemesh PS. Is there a Gynemesh PS surgeon resource monograph like there is for the Prolift and TVT?
A. I can't recall.
Q. But there is professional education materials for the Prosima device, correct?
A. That's correct.
Q. Do you recall if there's professional education materials for the Gynemesh PS device?
A. Not that I'm aware of.
Q. Is it your opinion that a monograph or professional education materials can be a substitute for the IFU in providing information about risks and complications to physicians?
A. Yes, I believe so.
Q. Do you know if -- under the

Page 215

federal rules or regulatory guidance if Ethicon is allowed to provide that kind of information in a source other than the IFU such as a monograph or professional education materials?
A. I don't know about that.
Q. Would you agree that unlike the IFU, Ethicon can't ensure that the monographs or the professional education materials reach every physician that uses the product?
MR. GAGE: Object to form.
A. Can you repeat that question, please.
BY MR. FAES:
Q. Would you agree that unlike the IFU, Ethicon has no way of ensuring that monographs or professional education materials reach every physician that uses the product?
A. I don't think they can ensure that the IFU reaches every physician. Sure, it's in every product, but that doesn't mean that every physician does look at it or read it.

Page 216

Q. But by placing the IFU in the box, Ethicon ensures that every physician has at least access to the IFU, correct?
A. Yes, I can agree with that.
Q. If Ethicon had put the same information that's in the monograph in their professional education materials in the IFU with regards to the risks of the device, they could have ensured that every physician who implants the device at least has access to that information, correct?
A. I'm sorry, can you repeat the question?
Q. If Ethicon had put the same information in the monograph -- strike that.
If Ethicon had put the same information that's in the monograph and professional educations in their IFU with regard to the risks and adverse reactions of the device, they could have ensured that every physician who implants the device at least has access to that information, correct?
A. Sure.

Page 217

Q. Once an IFU is out there, if Ethicon learns of a risk or complication that was not previously warned about and it was a significant risk or complication in terms of the harm it could cause to a woman, do you know whether or not Ethicon had any obligation to get that out to doctors?
A. Could you repeat that, please.
Q. Sure. Once an IFU is out there, if Ethicon learns of a risk or complication that was not previously warned about and it's a significant risk or complication in terms of the harm it could cause to a woman, do you know whether or not Ethicon had any obligation to get that out to doctors?
MR. GAGE: Object to form.
A. I don't know.
BY MR. FAES:
Q. I just want to backtrack a little bit on the IFU -- the 2015 Gynemesh IFU that was put out there.
Do you think it would have been reasonable for Ethicon to send a letter, a

Page 218

"Dear Doctor" letter out to physicians when they put that IFU out telling them that, hey, we've added some adverse reactions to this IFU that were not previously in the IFU?
A. Sure, I think that's reasonable. I don't think it's necessary, but it's reasonable.
Q. Do you know whether or not that occurred?
A. I don't know.
Q. Do you think it would have been reasonable in 2013 for Ethicon to send a letter out to physicians that -- informing them that, hey, we've changed the indications for use for this mesh so that it is no longer indicated for transvaginal mesh placement? Do you think that would be reasonable?
A. Sure, I think it's reasonable.
Q. Do you think it would have been reasonable for them in this letter to also tell physicians that the only reason that the FDA is still allowing this product to be sold is because it agreed to remove the transvaginal indication and change the

Page 219

indication to only be placed abdominally?
MR. GAGE: Object to form.
A. I don't think that's reasonable or necessary. That sounds excessive to me.
BY MR. FAES:
Q. You don't think a reasonable physician would want to know that the only reason the FDA is still allowing the Gynemesh PS to be sold is because Ethicon agreed to remove the transvaginal use indication from the IFU?
MR. GAGE: Object to form.
A. I don't think so.
BY MR. FAES:
Q. Do you know whether or not Ethicon did indeed send out a letter to physicians informing them that the indications for use for the Gynemesh PS device changed?
A. I don't know.
Q. Do you think it would be reasonable for Ethicon to put some kind of an indication on the Gynemesh PS box that contains the device either with a call-out on

Page 220

the box or a sticker informing physicians that, hey, the indications for this use have changed; you might want to read them? Do you think that would be reasonable?
MR. GAGE: Object to form.
A. Again, I think it's reasonable, but it's not necessary.
BY MR. FAES:
Q. So even though that you -- even though you've testified that you don't generally review the IFU, again, once you've used a product for the first time, you don't believe it's necessary?
A. Correct.
Q. You don't think that that's something that physicians would want to know or have their attention drawn to, that, hey, the indications for this device may have changed since the last time you used it?
A. I can -- I can't speak for all physicians. I'm speaking for myself. That for me, it wouldn't be necessary.
Q. If the overall consensus among a medical devices company's expert is that it

Page 221

would be a mistake to launch the device onto the market, do you think it would be wrongful for the company to launch that device anyway if the motivation is only to make a profit?
MR. GAGE: Object to form.
A. Can you repeat that question, please.
BY MR. FAES:
Q. Sure. If the overall consensus among a medical device company's expert is that it would be a mistake to launch that device onto the market, do you think it would be wrongful for the company to launch that device anyway if the only motivation is to make a profit?
MR. GAGE: Object to form.
A. Well, it depends on why they think it's a mistake. I mean, obviously the purpose of corporations is they have to make a profit with whatever they do. So it depends on what the -- why -- what they're -- why they're saying it's a mistake.
BY MR. FAES:
Q. If the company's experts

Page 222

believe it's a mistake to launch that particular device on the market because it is not more safe or effective than alternative treatment options, do you think it would be wrongful for the company to launch that device anyway?
A. I can't answer that yes or no. It really depends on the details of the product. There may be some other advantages, some other factors involved.
Q. If the overall consensus about a medical device -- strike that.
If the overall consensus among the medical device company's experts is that it would be a mistake to launch a particular device onto the market, do you think the doctors and patients who are sold that device should know that information?
A. I think it's more -- no, because I think it's more important that there's data showing the results, that there's studies that show the results of what happened and not their -- just those opinions.

Page 223

Q. So you don't think that that's information that doctors or patients would want to know, is that the company had asked their experts what they thought about the device and the experts told the company, this is a big mistake, don't do it?
MR. GAGE: Object to form.
A. I don't know what other doctors and patients would want to know.
BY MR. FAES:
Q. Do you know whether scar contracture around the mesh can occur with the Gynemesh PS?
A. Yes, it can. As in every pelvic surgery, there's going to be scar contracture if you just cut on the vagina.
MR. FAES: Object and move to strike after the answer "yes, it can."
BY MR. FAES:
Q. Do you know whether or not that was a problem that Ethicon's engineers were trying to solve by designing a better mesh?
A. I don't recall.
Q. Would you agree that scar

Page 224

contracture can translate into procedural complications?
A. Yes, it can.
Q. Do you know whether or not in 2005, physicians were asking Ethicon for a mesh which would be better than the Gynemesh PS in the area of scar contracture?
A. I don't know.
Q. Would you agree that scar contracture can cause recurrence of prolapse?
A. No, I disagree with that.
Q. Would you agree that scar contracture can cause pain?
A. Yes, I agree with that.
Q. Would you agree that scar contracture can cause stiffness?
A. Stiffness?
Q. Yes. Stiffness of the mesh. I'll rephrase. Would you agree that scar contracture can cause stiffness of the mesh?
A. No, I don't think it causes stiffness of the mesh.
Q. Would you agree that scar contracture can cause a stiff scar tissue?

Page 225

A. Yes, it can do that with or without mesh.
MR. FAES: Object and move to strike after the answer "yes."
BY MR. FAES:
Q. Would you agree that scar contracture can cause erosion?
A. No.
Q. Would you agree that scar contracture can cause discomfort during sex?
A. Yes. That can occur with or without the presence of mesh.
MR. FAES: Object and move to strike after the answer "yes."
BY MR. FAES:
Q. So you disagree that scar contracture can cause recurrence of the prolapse or erosion, correct?
A. That's correct.
Q. So if physicians were reporting to Ethicon that scar contracture can cause recurrence of the prolapse and erosion, you would disagree with those physicians?
A. Yes.

Page 226

Q. Would you agree that for mesh to be successfully used for the treatment of pelvic organ prolapse, it should be soft and compliant with a woman's vaginal tissues?
A. Ideally, yes.
Q. Would you agree that a mesh could be too stiff for the treatment of pelvic organ prolapse?
A. Yes, it's possible.
MR. FAES: Can we go off the record for a quick second.
(Recess Taken From 10:00 a.m. To 10:09 a.m.)
BY MR. FAES:
Q. Dr. Pramudji, we're back on the record after a short break. Are you ready to proceed?
A. Yes.
Q. You know that the Gynemesh PS is, in fact, less stiff than the traditional Prolene mesh used for hernia repairs, correct?
A. Yes.
Q. And, in fact, that's a positive

Page 227

thing --
A. Yes.
Q. -- you would agree --
A. Yes.
Q. -- for use in vaginal tissues, correct?
A. Yes, I agree.
Q. Have you ever considered using traditional Prolene mesh for the treatment of pelvic organ prolapse?
A. No.
Q. Have you ever considered using traditional Prolene mesh for use in vaginal tissues?
A. No.
Q. Would you ever consider using it?
A. I don't think so.
Q. Would you never -- not consider using it because it's generally too stiff to be compliant with vaginal tissues?
A. That's correct.
Q. Would you agree that clinically there may be an impact with increased

Page 228

rigidity with any given mesh as it may increase vaginal stiffness postoperatively with a potential to impair sexual function?
A. Could you repeat that, please.
Q. Sure. Would you agree that clinically there may be an impact of increased rigidity with any given mesh as it may increase vaginal stiffness postoperatively with a potential to impair sexual function?
MR. GAGE: Object to form.
A. That could occur with some meshes that are more stiff.
BY MR. FAES:
Q. Would you agree that any future meshes developed by Ethicon for the treatment of pelvic organ prolapse should be less rigid than the Gynemesh PS?
A. No, I don't agree with that.
Q. So if Ethicon's medical directors believe that that was an appropriate goal, you would disagree with them?
A. I would say that the

Page 229

Gynemesh PS is an appropriate stiffness of mesh, but I wouldn't disagree with trying to make a less stiff mesh and see if it behaved -- if the results are as good.
Q. Do you know whether or not, as of 2009, it was Ethicon's goal that all future meshes developed by Ethicon for pelvic organ prolapse should be less rigid than the Gynemesh PS?
MR. GAGE: Object to form.
A. I don't know.
BY MR. FAES:
Q. Would you agree that clinical trials show that large-pore meshes in general provide better patient comfort than standard meshes?
MR. GAGE: Object to form.
BY MR. FAES:
Q. Strike that. I'm going to withdraw that and ask a different question.
Would you agree that clinical trials show in general that large-pore meshes provide better patient comfort than standard meshes and that the reason for that is due to

Page 230

lower scar tissue formation and lower stiffness?
MR. GAGE: Object to form.
A. What are the standard meshes that you're referring to?
BY MR. FAES:
Q. A standard mesh would be, for example, the standard Prolene mesh or the standard Marlex mesh, which is now called the Bard mesh.
A. Okay. I understand. So the answer -- you'd better repeat the question so I make sure I answer properly.
Q. Sure. Would you agree that clinical trials show that large-pore meshes provide better patient comfort than standard meshes and the reason is due to lower scar tissue formation and lower stiffness?
A. Yes, that's correct.
Q. Are you aware that Ethicon was told by its top consultants that it didn't make sense to use the Prosima in people with lesser degrees of prolapse given the outcomes?

Page 231

MR. GAGE: Object to form.
A. I'm not aware of that.
BY MR. FAES:
Q. Do you know how the mesh in the Prolift is cut?
A. I believe it's machine cut.
Q. You believe that the mesh in the Prolift is machine cut?
A. Yes.
Q. Do you know how the mesh in the Prosima is cut?
A. I believe it's also machine cut.
Q. Do you know how the mesh in the Gynemesh PS flat sheets is cut?
A. Not sure about that one.
Q. Do you know whether or not the cutting method for Prolene mesh affects the rigidity or stiffness of the mesh?
A. It does not.
Q. So it's your opinion that -- to a reasonable degree of medical certainty, that the cutting method for the Prolene mesh, whether it be mechanical, laser cut or

Page 232

ultrasonically cut, has no effect on the stiffness or rigidity of the mesh?
A. That's correct.
Q. Have you seen any studies that Ethicon has done with regard to the difference in stiffness between ultrasonically cut and laser cut mesh?
A. Not that I can recall, as I sit here right now.
Q. If Ethicon did a study comparing ultrasonically cut mesh to laser cut mesh and found that one of those meshes was stiffer than the other, you would disagree with those findings?
MR. GAGE: Object to form.
A. I would -- I would have to look at it, but I don't think it would make any clinical difference at all, because half the time you end up trimming the edges anyway, which is where the cut edge is. So it ends up being mechanically cut no matter what.
BY MR. FAES:
Q. Would you agree that when you cut the Gynemesh PS with a pair of scissors,

Page 233

whether it's the Prolift, the Prosima or the flat sheets, that there can be sharp edges after the mesh is cut?
MR. GAGE: Object to form.
A. No, they're not sharp edges. They're floppy fibers.
BY MR. FAES:
Q. So you don't believe that there can be a sharp edge on the Gynemesh PS mesh after it's cut with scissors?
A. No, no sharper than a suture that you would have.
Q. You don't believe that a potential risk -- strike that.
You don't believe that there can be a sharp edge after cutting the Gynemesh PS with the scissors and the potential risk of that sharp edge is that it can cause erosion or pain or protrude through the woman's delicate vaginal tissues; is that correct?
A. That's correct.
Q. And if Ethicon scientists and engineers who were assessing the risks of the

Page 234

Gynemesh PS mesh found that that was a potential risk, you would disagree with them?
MR. GAGE: Object to form.
A. Yes, I disagree with them. That's not what we see in clinical practice.
BY MR. FAES:
Q. If other doctors told Ethicon that they were concerned that there was a risk of sharp edges after the Gynemesh PS mesh was cut that could be sharp and cause erosion or pain or complications, you believe those doctors are wrong and their fears are unfounded?
MR. GAGE: Object to form.
A. I'm not sure what they're doing or how they're implanting it, but when you cut the mesh, the edges are no sharper than they were before you cut it. And the mesh itself is not going to just start poking through. Either it's not placed in the right plane or the patient has poor wound healing. It doesn't just cut through. It's not like that at all. It's soft and floppy.
BY MR. FAES:

Page 235

Q. Okay. I'm going to have to re-ask that question because I think the answer you gave me is a little bit different --
A. Sorry.
Q. -- than the answer I was looking for.
If other doctors told Ethicon that they were concerned about sharp edges in the Gynemesh PS after it was cut with the scissors and that those sharp edges could potentially protrude through vaginal tissue and cause pain, do you believe that those physicians' fears are unfounded?
MR. GAGE: Object to form.
A. Yes, I disagree with those physicians.
BY MR. FAES:
Q. If those same physicians were concerned that particles could be released when the Gynemesh PS was cut through scissors -- strike that.
If those physicians were concerned that particles could be released

Page 236

when the Gynemesh PS was cut with scissors and that those particles could become lodged in a woman's vaginal tissues and cause potential complications, do you believe those physicians' fears are unfounded?
MR. GAGE: Object to form.
A. Absolutely.
BY MR. FAES:
Q. Doctor, are you going to offer -- do you plan to offer an opinion in this case about your personal success rate with the Prosima, Prolift or Gynemesh products?
A. Yes.
Q. What is the opinion you intend to offer about your personal success rate with those products?
A. What I found is that the products were very successful with a high patient satisfaction with few complications.
Q. Do you intend to offer a numeric success rate --
A. No, I don't have a --
Q. -- in conjunction with those

Page 237

products?
A. No, I don't have a calculated numeric rate for my patients.
Q. Same question with regard to complication or erosion or extrusion rates, do you intend to offer an opinion in this case with regard to a numeric percentage of complications or erosions or extrusion rates that you've experienced personally?
A. Perhaps. I have in the past calculated reoperation rates, but I can't recall right now if it was on Prolift or on TVT. I would have to go back and look at my operative logs.
Q. So --
A. So I may have that rate on --
Q. Just reoperation rates?
A. Correct, just reoperation rates.
Q. Not exposure or extrusion rates?
A. Correct.
Q. Can you tell me how you arrived at those reoperation rates?

Page 238

A. I took my total number of reoperations and my total number of cases and just divided it.
Q. And what --
A. So it's a rough number.
Q. And what is the numerator and denominator for those?
A. I don't recall, as I sit here right now. I would have to look at it.
Q. And who did -- who did the review?
A. Myself.
Q. Is there any documentation regarding the review or your findings that you used to come up with those rates?
A. I have an operative log that I keep.
Q. Do you know if that's been produced to us in this litigation?
A. No, I don't believe so.
MR. FAES: We would ask that that would be produced if the doctor is going to offer any opinions about her reoperation rates at trial.

Page 239

MR. GAGE: I'll consult with her and let you know what our position is on that.

BY MR. FAES:

Q. Did you do any kind of analysis of patients that were lost to follow-up?

A. No, I did not.

Q. What time frame were you using for your reoperation rates to come up with your reoperation rate number for Prolift and Prosima?

A. Well, I just -- just from the -- when I started using the products until I did the analysis, however many years that was. I can't remember when I did that analysis.

Q. But you can't state a specific year that you started and stopped?

A. No, I can't remember right now.

Q. But it's fair to say it would go back to when you were working in Dallas in Dr. Anhalt's practice, correct?

A. Well, yeah. It wasn't in Dallas. It was here in Houston. But, yes,

Page 240

back to 2005, when I started doing the Prolift, until I did the analysis, because there may have been some complications that were treated after I stopped using the products. But I can't remember when I did that.

Q. And if a doctor [sic] needed a reoperation and went to a different doctor other than you, you wouldn't have that information unless the patient shared it with you, correct?

A. That's correct.

Q. So your reoperation rates that you calculated would exclude any patients that went to other doctors for reoperation that you didn't know about, correct?

A. Yes. But kind of what I did in reverse, which this is very rough, but I included patients that came from other doctors in my reoperation rate. So some patients were not my original -- I was not the original implanter. So it's kind of -- it's a very rough analysis. There's just sort of, okay, I did this many implants; how

Page 241

many reoperations did I do? And this is just -- this isn't even -- this is just like a mesh exposure, mesh explant-type reoperation. It's not comprehensive.

Q. Okay. I think you've answered my question on that.

I hate to do this to you, but since there's no invoices yet on your case-specific depositions that you're going to be offering opinions on, I need to go through and ask you if you have a rough estimate of the number of hours you've spent on each of your cases. Do you know approximately how many hours you've spent on the Sharon Carpenter case?

MR. GAGE: Let me just say, I assume that by doing this that the individual lawyers will not ask the question and that you would agree as liaison counsel that I can say "asked and answered," we don't have to do it during the individual cases?

MR. FAES: Well, they might ask more specific questions, like break

Page 242

down the amount or whatever, but, yeah, you can certainly object.

MR. GAGE: Okay.

BY MR. FAES:

Q. Do you recall how many hours you've spent on the Sharon Carpenter case?

A. I don't recall.

Q. Do you recall how many hours you've spent on the Mary Jane Olson case?

A. I don't remember.

Q. You don't have any kind of estimate, as you sit here today, or any documentation regarding how many hours you've spent on that case?

A. I would say maybe 30 to 50 hours on each case, let's say. That may be high; that may be low. It depends. Some of them are more complicated than others.

Q. So you estimate -- your best estimate, as you sit here today, on all the cases, case-specific cases that you are going to offer opinions on in the next couple of days, is that you spent approximately 30 to 50 hours on each of those cases?

Page 243

A. Uh-huh. Yes.
Q. And that rate at this point that you've charged for those cases is $600 an hour for review?
A. Correct.
Q. And your deposition testimony will be 700 an hour, correct?
A. Correct.
Q. And that's the same rate as if you get called for trial?
A. Correct.
(Deposition Exhibit 14 marked.)
BY MR. FAES:
Q. Doctor, I'm going to hand you what's been marked as Exhibit No. 14 to your deposition.
(Witness Reviews Document.)
BY MR. FAES:
Q. Doctor, this is an e-mail from you to Robert Zipfel, Z-i-p-f-e-l, at Ethicon responding to a press release regarding the launch of the Prolift+M; is that correct?
A. Correct.
Q. I'm not going to ask you about

Page 244

this whole thing, but if you go down to the third paragraph, it says, "This lightweight" -- with regard to the Prolift+M, it says, "This lightweight polypropylene mesh is less dense and has larger pores than previous meshes, which could lead to decreases in reactive scar formation and a reduction in inflammatory response during healing. This mesh also has properties that help the surgeon place the mesh more easily because it resists wrinkling and folding, and it has increased longitudinal elasticity while maintaining lateral support to ensure pliability after surgery. The new design may improve vaginal wall compliance and allow for better tissue incorporation."
Do you see that?
A. Yes.
Q. Is this your understanding of what Ethicon believed were the potential benefits of the Prolift+M device?
A. Yes, that's my understanding.
Q. And you know that this Prolift+M device uses a mesh that has pores

Page 245

that are lighter weight and larger pore than the mesh used in the original Prolift device, correct?
MR. GAGE: Object to form.
A. I think -- you said the pores are lighter weight. I don't know if that's what you meant to say.
BY MR. FAES:
Q. That's not what I meant to say.
A. Okay.
Q. I'll re-ask the question. And you know that this Prolift+M device uses a mesh that has larger pores and is of a lighter weight than the mesh used in the original Prolift device, correct?
A. I believe after the Monocryl is observed, then it becomes a lighter-weight mesh.
Q. In fact, it becomes almost half the weight of the mesh used in the Prolift; isn't that correct?
A. That sounds about right.
Q. And this Prolift+M device, you would agree, did ultimately become your

Page 246

device of choice over the Prolift for the treatment of pelvic organ prolapse?
A. Yes.
Q. That's all the questions I have about that document.
A. Okay.
(Deposition Exhibit 15 marked.)
BY MR. FAES:
Q. Doctor, I'm going to hand you what's been marked as Exhibit No. 15 to your deposition.
A. Okay.
Q. And I just have a real quick question about this. This is a document dated February 27th, 2008, titled "Prosima Launch Plan." And if you turn to the second page under "Southern Region," you see that your name is listed as the third name on the first column. Do you see that?
A. Yes.
Q. Does this document indicate that you were one of the initial preceptors for the launch of the Prosima device?
A. It looks like I was targeted

Page 247

for that, but, honestly, I can't remember the timeline on that.
Q. Do you remember if you were one of the initial preceptors for the Prosima device?
A. I don't remember.
Q. So you could've been or you might not have been; you just don't know one way or the other?
A. Yes, I can't remember.
Q. That's all the questions I have for that document.
(Deposition Exhibit 16 marked.)
(Deposition Exhibit 17 marked.)
BY MR. FAES:
Q. I'm going to hand you what's been marked as Exhibits 16 and 17.
Doctor, Exhibit No. 16 is an e-mail dated January 13th, 2009, regarding a urology meeting follow-up. Do you see that?
A. Yes.
BY MR. FAES:
Q. If you turn to the fourth page where it discusses the "Blue Group," you see

Page 248

that you are listed, as the sixth name down, as participating in this group. Do you see that?
A. Yes.
Q. Do you remember participating in this group in 2009?
A. Vaguely.
Q. If you look down under "Recommendations to Group: Patient Education," the fourth bullet point down, it states, "Safety long-term communicate to patients, this eases their fears." Do you see that?
MR. GAGE: Object to form.
A. Yes, I see that.
BY MR. FAES:
Q. Did you -- was this a recommendation that you remember the team making to Ethicon?
A. I don't remember.
Q. Did you believe, at this time in 2009, it was important to ease the fears of patients with regard to the safety of mesh devices for the treatment of pelvic organ

Page 249

prolapse?
A. Well, this was right after the 2008 FDA notification, so that may have been where some of that sentiment came from. But I don't recall specifically any conversations at that conference.
Q. My question was actually a little bit different than that. So I'm going to re-ask it.
A. Okay.
Q. Did you believe, at this time in 2009, that it was important to ease the fears of patients with regard to the safety of mesh devices for the treatment of pelvic organ prolapse?
A. I'm sorry, can you repeat that one more time?
Q. Did you believe, at this time in 2009, that it was an important goal to ease the fears of patients with regard to the safety of mesh devices for the treatment of pelvic organ prolapse?
A. I can't remember what I thought at that time.

Page 250

Q. You see the second bullet point down, it says, "Google - have EWHU" -- which you know stands for "Ethicon Women's Health & Urology," correct?
A. Correct.
Q. -- "website precede litigation websites." You see that?
A. Yes.
Q. So one of the recommendations of the team was to pay Google to have Ethicon's website appear before any litigation websites on Google searches?
A. That's what it appears to be.
Q. Now, you stated that the litigation environment changed in 2012 and that's when you believed that pelvic organ prolapse devices should not be considered for first-line treatment, correct?
A. That's when it really seemed to ramp up.
Q. But, at least according to this document in 2009, fears about lawsuits were of concern going back to 2009 --
A. That's what it looks like --

Page 251

Q. -- is that correct?
A. -- according to this.
Q. Did -- do you recall at this meeting like -- do you recall if at this meeting you felt like Ethicon and physicians felt like you needed to do damage control to address the 2008 public health notification?
A. I don't recall.
Q. Would you agree that if the fear of being named in a lawsuit prevents someone from using a product that is unsafe, that that's a good thing?
A. Can you repeat that for me, please.
Q. Would you agree that if the fear of being named in lawsuits prevents someone from selling a product that is unsafe, that that's a good thing?
A. No, I don't think that's a good thing.
Q. Well, you'd agree that asbestos in this country is generally no longer being sold, right?
A. I don't know anything about

Page 252

asbestos.
Q. You don't know anything about asbestos?
A. No.
Q. You don't know whether -- as a physician, whether or not asbestos causes cancer and is hazardous to human health?
A. I do know that it causes mesothelioma, but I don't know about the asbestos product line or market or lawsuits or anything like that.
Q. Would you agree that asbestos should never be used in a medical device?
A. I don't know why it would be used in a medical device.
Q. That's not my question. Would you agree that asbestos should never be used in a medical device?
A. I don't know. I don't know enough about it.
Q. You don't know whether or not it's harmful for asbestos to be placed in continuous contact with the human body?
A. Well, I know that inhalation of

Page 253

asbestos fibers can cause lung cancer, but beyond that, I really don't have an opinion.
Q. So if fear of being sued prevented a company from putting out an asbestos product that could be inhaled into the body and that was the only thing that kept that company from putting that product out, do you believe that would be a bad thing?
A. I don't know. I don't have an opinion about that.
Q. If you go to the last bullet point, "Recommendations to Group: Clinical Data," it says, "Do studies on ISD" -- which I assume is intrinsic sphincter deficiency -- "smokers, obesity and safety." Do you see that?
A. Yes.
Q. So at this time in 2009, one of the recommendations to Ethicon, that this group that you participated in, was that Ethicon needed more data on safety.
A. What it says here is they -- the recommendation was to do studies on

Page 254

safety. I don't -- that's all I can say about it.
Q. One of the other recommendations was that Ethicon get more data on how the mesh could be used in people who were obese or smoked.
A. That's what it says here.
Q. Does that indicate that at this time there wasn't sufficient data on how the mesh behaved in individuals who were obese or smoked?
A. I don't know. I would have to look at what studies were available at that time in 2008.
MR. FAES: William, I could go on, but I think I'm at about my two-hour limit.
MR. GAGE: Okay. I guess I do my follow-up?
MR. FAES: Yeah.
MR. GAGE: Let me take just a little break.
(Recess Taken From 10:41 a.m. To 10:53 a.m.)

Page 255

EXAMINATION
BY MR. GAGE:
Q. Dr. Pramudji, my name is William Gage, and I've got just a couple of questions for you. You were asked, I believe yesterday, some questions about the Prosima IFU. Do you recall that?
A. Yes.
Q. And in particular, some of the questions related to whether the IFU -- the Prosima IFU referenced anything about stage IV pelvic organ prolapse. Do you recall those questions?
A. Yes.
Q. Do you recall generally what the question that was posed to you was?
A. I think it was the indications for the Prosima for what stage it's indicated.
Q. And were you asked whether the Prosima IFU made any references with regard to stage IV?
A. I believe so.
Q. And do you remember what your

Page 256

answer was?
A. I did not think it made a reference to that.
Q. Okay. I'm handing you the Prosima IFU that today has been marked as Exhibit 11, and I'm showing you the warnings and precautions section of the IFU. Do you see that?
A. Yes.
Q. And the second bullet under "Warnings and Precautions" says, "Use of the Gynecare Prosima System has not been fully evaluated in patients with Stage IV pelvic organ prolapse. Therefore its use in these patients is not recommended."
Did I read that correctly?
A. Yes.
Q. What is the significance, if any, of that statement to your answers yesterday about stage IV and the Prosima IFU?
A. Yes. So the IFU indicates that it is not recommended for stage IV prolapse.
Q. And is that something you read that had just -- yesterday when you were

Page 257

asked about it had forgotten?
A. Yes, I had forgotten about that.
Q. Doctor, you were asked a number of questions yesterday and perhaps some today about certain opinions that you have where you disagree with the FDA. Do you recall those questions?
A. Yes.
Q. Are you alone among pelvic floor surgeons in disagreeing with the FDA on certain issues related to pelvic organ prolapse mesh?
A. No. As a matter of fact, there is a network of dozens of pelvic surgeons who have even issued statements disagreeing with the FDA.
Q. And at a high level, what are those disagreements with regard to pelvic organ prolapse mesh?
A. The disagreements are that -- the statement that the complications are not rare, because the literature and the personal use indicates that the complications are

Page 258

rare. And also that the benefits of mesh are in question; whereas studies, particularly for a cystocele repair, indicate that there is a definite benefit in efficacy using mesh implants.
Q. You have been asked some questions yesterday and today about whether the mesh in Prosima, Prolift and Gynemesh PS was cut with a machine or cut with a laser. Do you recall those questions?
A. Yes.
Q. What is the clinical significance, if any, as to whether the mesh in those three devices is cut by a machine with a blade or cut by a laser?
A. There's really no clinical impact one way or another as far as efficacy or complications. And particularly, as I mentioned earlier, most surgeons are going to trim the edges of the mesh to some degree or another, usually quite extensively, and therefore the edges effectively all become scissor cut when they're implanted.
Q. Doctor, how long have you been

Page 259

working with Ethicon on the pelvic organ prolapse mesh litigation? Do you recall when you were first retained?
A. I think it was three years ago, if I remember correctly.
Q. Is it fair to say that you've reviewed a lot of materials going back to that date?
A. Yes.
Q. And some of that would include company documents?
A. That's correct.
Q. And would you have also reviewed patient medical records?
A. Yes.
Q. You testified earlier that you were unaware that the indications section of the Gynemesh PS IFU had been changed recently. Do you recall that?
A. Yes.
Q. Is it possible that that was a fact that you knew from your prior and earlier work on the pelvic organ prolapse litigation, but it is something that when you

Page 260

were asked that question you had forgotten?
A. Yes, that's entirely possible, with all the voluminous information I've tried to absorb.
MR. GAGE: That's all I have.
MR. FAES: Just a couple of questions, Doctor.
FURTHER EXAMINATION
BY MR. FAES:
Q. With regard to the Prosima IFU, you'd agree that in the indications-for-use section, there's nothing in the IFU that says that the Prosima should only be used for grades II and III prolapse, correct?
A. In that section, that is correct.
Q. You'd agree that there's nothing in that section that informs physicians that it shouldn't be used for a grade IV prolapse, correct?
A. That's correct.
Q. In fact, there's no contraindication in this section informing physicians that it's not indicated for

Page 261

grade IV prolapse.
A. That's correct.
Q. You said that there are other pelvic floor surgeons who disagree with the FDA and that there are organizations of those physicians. What are those organizations?
A. I think it's called the Pelvic Floor Mesh Network.
Q. Are you a member of that organization?
A. I signed on to the communication. It's not -- I don't know that it's an organization per se, or if it was just a consortium of surgeons that were all of like mind as far as pelvic surgery.
Q. Do you know how many surgeons belong to that organization?
A. Seems like there were dozens on the e-mails. But I don't know an exact number.
Q. You don't know a number --
A. No.
Q. -- as you sit here today? So it's possible that this is an organization of

Page 262

outlier physicians who disagree with the FDA since you don't know the number of physicians that belong to this group?
A. No, these were mainstream surgeons, prolific users that had a lot of experience and had --
Q. How do you know that there're mainstream users who are other members of this organization?
A. Well, in particular I remember Dr. Lucente, Dr. Supulveda. That's all I can remember off the top of my head. But it was people that I was familiar with that -- professors, people that had a lot of experience with pelvic mesh that had seen how it actually behaved in patients.
Q. You know that Dr. Supulveda is an expert in mesh litigation, correct?
A. Yes.
Q. You know that Dr. Lucente is an expert in mesh litigation, correct?
A. I didn't know about that.
Q. You know that Dr. Lucente has received over a million dollars from Ethicon

Page 263

for his consulting work related to mesh, correct?
A. I don't know about that.
MR. GAGE: Object to form.
BY MR. FAES:
Q. If those -- if that's true, that Dr. Lucente has received over a million dollars, wouldn't that present a conflict for him when he had a financial incentive to support the continued use of mesh?
A. No. I don't see that as a major conflict.
Q. You don't think a person who's made over a million dollars off of mesh consulting would have an incentive to have the use of mesh continue?
A. You know, I think it's fair for physicians to be compensated for their time. You want people that use it a lot to be your consultant and to train other people and they need to be compensated. So I don't know -- I don't see how you can avoid that issue. I don't -- and I can't speak to his motivation.
MR. FAES: I'm going to object

Page 264

and move to strike as nonresponsive. I'm going to re-ask it because I don't think you've answered my question.
A. Sorry.
BY MR. FAES:
Q. Do you think a person who's made over a million dollars off of mesh consulting would have an incentive to see the use of mesh continue?
A. I don't know.
Q. Are there any other organizations you're aware of that disagree with the FDA's stance on pelvic mesh other than the Pelvic Floor Mesh Network?
A. Not that I can think of right as I sit here.
Q. You specifically said that one of the things that the FDA said that this organization disagrees with is that complications associated with pelvic organ prolapse mesh are not rare; is that correct?
A. That's correct.
Q. Do you consider an event that occurs in one out of five people to be rare?

Page 265

A. No, I would -- I would say -- I would say that's not rare.
Q. Would you say an event that -- an adverse event that occurs in one out of five patients is common?
A. I wouldn't say common.
Q. But you would agree that it's not rare?
A. Yeah, I would not call that rare.
Q. You state that you know of -- you don't believe there's a clinical impact between the use of laser cut or mechanically cut mesh. Are you aware of any clinical study that specifically looked at the safety as a primary end point between laser cut and mechanically cut surgical mesh?
A. Not that I can think of right now.
Q. Do you believe that you at one point knew that the indications for use for the Gynemesh PS had changed in 2013 and just forgot?
A. Yes. I just forgot about that.

Page 266

Q. Do you feel like that's an important fact that you should know in rendering an opinion about whether or not the Gynemesh PS, Prolift and Prolene Soft is defective?
A. No, I don't think it matters one way or another.
MR. FAES: That's all the questions I have.
MR. GAGE: I don't have any follow-up.
(Deposition Concluded At 11:06 a.m.)
--o0o--

CERTIFICATE

I, MICHEAL A. JOHNSON, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, CHRISTINA PRAMUDJI, M.D. was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was not requested by the witness or other party before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____
MICHEAL A. JOHNSON, RDR, CRR
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Reporter
Certified Court Reporter

Notary Public in and for the
State of Texas
My Commission Expires: 8/8/2016

Dated: March 24, 2016

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I, CHRISTINA PRAMUDJI, M.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
CHRISTINA PRAMUDJI, M.D. DATE

Subscribed and sworn to before me this
_______ day of _______________, 20 _____.
My commission expires: _______________

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Notary Public

LAWYER'S NOTES

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